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09/787,806	04/26/2001	Brian Anthony Whittle	65,213-001	9829

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/26/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/787,806

Applicant(s)

WHITTLE, BRIAN ANTHONY

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and request for continued examination, all received on 13 August 2003.

Claim Rejections - 35 USC § 101 and 112

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 provides for the use of calcium oxide and anhydrous or calcined MgSO_4 , but since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex*

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parte Dunki, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1 and 4-16 under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.* in view of Wilen, Needleman *et al.*, Theeuwes, and Buysch *et al.* is maintained.

Claims 1 and 4-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takaichi *et al.* in view of Wilen, Needleman *et al.*, Theeuwes, Gurol *et al.* (U.S. Patent No. 6,066,342), Buysch *et al.* and Galat (U.S. Patent No. 5,776,431)

The Takaichi *et al.* document discloses a method of stabilizing pharmaceutical compositions by the use of calcium oxide and particulate silicon dioxide to control moisture and restrict the interaction of water with other components of the composition (See Abstract; Page 2, Line 12 to Page 3, Line 22). The amount of calcium oxide to be included in the composition is not to exceed 1.0 % by weight (See Page 4, Lines 10-21). A sour agent is also to be used and may be an organic acid, including citric acid and ascorbic acid (See Page 6, Lines 11-15). Other components, such as binders, excipients, and disintegrators may also be included, and the composition may be prepared using methods already known in the art (See Page 6, Line 16 to Page 7, Line 5).

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The Takaichi *et al.* patent does not teach a composition comprising magnesium sulfate, either as the sole anhydrous compound, or in combination with calcium oxide, with either compound not exceeding 10% by weight of the composition. The patent also does not teach a composition that further comprises an acid or acid salt and a carbonate or bicarbonate in an effervescent composition. The patent does not teach a composition that further comprises a sulfite or calcium lactate.

The Wilen patent teaches an effervescent pharmaceutical composition comprising dried magnesium sulfate, and an effervescent base, which may include sodium bicarbonate and citric acid (See Example 2). Although the precise amount of magnesium sulfate is left to be determined by one of ordinary skill in the art, based on the disclosure of a previous example (See Example 1), it would be obvious that magnesium sulfate would be present in a quantity less than 10% by weight of the composition.

The Needleman *et al.* patent teaches an effervescent composition (See Abstract). The effervescent agent in the composition comprises an alkaline carbonate salt, which may be chosen from a group comprising sodium bicarbonate, sodium carbonate, potassium bicarbonate, potassium carbonate, magnesium carbonate, calcium carbonate, and combinations thereof (See Column 2, Lines 24-41). The effervescent agent further comprises an acid, which may be chosen from a group comprising tartaric acid, maleic acid, lactic acid, citric acid, ascorbic acid, sodium sulfite, potassium sulfite, and combinations thereof (See Column 2, Lines 42-61). The composition further comprises an exothermic agent, which may be chosen from a list that includes calcium oxide and magnesium sulfate (See Column 3, Lines 3-20). Furthermore, Needleman *et al.* disclose a problem known in the prior art of the moisture sensitivity of

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effervescing ingredients, and the need to avoid contact with even ambient humidity in order to preserve the shelf life of an effervescing product (See Column 1, Lines 36-50).

The Theeuwes patent teaches an osmotic device that dispenses a drug by the use of a gas-generating means (See Abstract). The gas-generating means preferably comprises a solid acid component and a solid basic component. Among the acids that may be used is malic, tartaric, maleic, and citric acid. Alternately, their corresponding anhydrides may be used as well. The solid basic component is preferably includes the carbonates and bicarbonates of alkali metals and alkali earth metals and mixtures thereof (See Column 4, Line 60 to Column 5, Line 36). The patent also mentions the use of a water scavenging process to control the acid-base reaction of the effervescing action (See Column 5, Lines 37-50). An osmotically effective compound may also be included in the composition to aid in the effervescing action. Such compounds include magnesium sulfate, sodium carbonate, sodium sulfite, calcium bicarbonate, and calcium lactate; mixtures of these compounds may also be used (See Column 7, Lines 1-30).

The Gurol *et al.* patent discloses that in over-the-counter antacid compositions, magnesium salts are used in combination with calcium carbonate in order to counteract the constipating effects of calcium carbonate (See Column 1, Line 57 to Column 2, Line 2).

The Buysch *et al.* patent is relied upon here as a teaching reference that acknowledges the dessicating properties of calcium oxide and magnesium sulfate in the prior art (See Column 5, Lines 14-38).

The Galat patent is relied upon here as a teaching reference that shows that the constipating effects of calcium salts and the laxative effects of magnesium salts are known in the prior art.

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It would be obvious to one of ordinary skill in the art to combine the teachings of Takaichi *et al.*, Wilen, Needleman *et al.*, Theeuwes, Gurol *et al.*, Buysch *et al.*, and Galat into the object of the instant application. Wilen, Needleman *et al.*, and Buysch *et al.* all teach various effervescent compositions. As stated in *In re Kerkhoven*, 205 USPQ 1069, 1072 (CCPA- 1980), “It is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose.” As this court explained in *Crockett*, 126 USPQ 186, 188 (CCPA- 1960), the idea of combining them flows logically from their having been individually taught in the prior art. One of ordinary skill would be motivated to combine these three references in order to gain a more complete understanding of the substances that may be included in an effervescing composition. Based on the disclosure in Needleman *et al.* regarding the moisture sensitivity of effervescing compounds, one of ordinary skill would be motivated to combine the teachings Takaichi *et al.* and Buysch *et al.* with the combined teachings of Wilen, Needleman *et al.*, and Buysch *et al.* in order to formulate a composition that prevents interaction of water with the effervescing components of said composition, improving stability and shelf life. The Galat patent shows that the pharmacological side effects of calcium and magnesium salts are known in the art, and the Gurol *et al.* patent shows that the combination of a calcium salt and a magnesium salt are known in the art for the express purpose of counteracting the constipating effects of the calcium salt. One of ordinary skill in the art therefore would be further motivated to use a calcium salt and a magnesium salt in combination with each other in a pharmaceutical composition.

Thus, the invention as a whole is *prima facie* obvious.

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Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The objection of Claims 12 and 13 under 37 CFR 1.75 as being a substantial duplicate of Claims 4 and 5, respectively, is hereby withdrawn with the amendment of Claims 12 and 13.

Response to Arguments

Applicant's arguments filed 13 August 2003 have been fully considered but they are not persuasive.

The applicant's arguments are based on what the examiner believes to be a narrow interpretation of both the claims and the prior art. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

The applicant asserts that "an invention is not obvious where "old" or "well known" elements solve different problems". However, the examiner finds this statement to be entirely unpersuasive and invites the applicant to explicitly point out where this has been established.

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The examiner would also like to remind the applicant that the claiming of a new use, new function or unknown property, which is inherently present in the prior art, does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). See MPEP § 2112. In either rejection of the claims under 35 U.S.C. 103(a), it is the position of the examiner that the calcium oxide, inherently possessing both a desiccating and a constipating property, would have the constipating property counteracted by the inclusion of the magnesium salt, which inherently possesses a laxative property and a desiccating property.

The applicant has not shown how the particular selection of a calcium salt and a magnesium salt in specific quantities would not have been within the purview of one of ordinary skill in the art at the time the instantly claimed invention was made. It is the position of the examiner that these selections, as claimed by the applicant, would have been attainable through the course of routine experimentation and optimization. The pending claims remain rejected.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sj0

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